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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,977	07/14/2003	Brian L. Bates	003006-002480	5904

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111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER	
SWEET, THOMAS	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
10/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,977	BATES ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/15/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,36,38,40-44,46-49 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,36,38,40-44,46-49 and 51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 35-54 have been considered but are moot in view of the new ground(s) of rejection. Although, Roger et al. (Ceramide-Coated Balloon Catheters Limit Neointimal Hyperplasia After Stretch Injury in Carotid Arteries) preferred embodiment is Ceramide, it also blanketly discloses lipophilic bioactive material in general as in the previous and current rejection. Regarding "the portions of the dried layer containing paclitaxel are positioned in the folds", this is read a the agent being on the whole surface no just the folds, so a coated stent when folded meets these limitations. Regarding claim 36, applicant did not rebut the well known practice of inflation time up to about one minute (inherent in that angioplasty is done in 45-60 second inflation times with deflation time in between inflations to allow life giving blood flow), so this is now admitted prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-36, 38, 40-44, 46-49 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roger et al (Ceramide-Coated Balloon Catheters Limit Neointimal Hyperplasia After Stretch Injury in Carotid Arteries) in view of Barry et al (6306166) in view of

Fischell (6,120,533). Roger et al. discloses a method of delivering a lipophilic bioactive material to an inner wall of a blood vessel of a patient from an implantable medical device having an expandable balloon with the lipophilic bioactive material on an outer surface of the balloon (page 288 lines 11-14 1st col), the method comprising the steps of:

Providing an angioplasty balloon having a dried layer containing the bioactive material on the outer surface of the balloon (page 283, line 26, 1st col, drying under nitrogen), the balloon being free of a coating atop the dried layer, the balloon being free of a time-release layer, the balloon being free of a containment material and the balloon being free of a containment layer (i.e. "lipid directly at the site", lipid in solvent dried directly to the balloon);

advancing the balloon within the blood vessel to a treatment site within the blood vessel;

inflating the balloon at the treatment site to contact the balloon with an inner wall of the blood vessel;

maintaining the inflated balloon in contact with the inner wall of the blood vessel so as to transfer lipophilic bioactive material to the inner wall of the vessel;

deflating the balloon after said; and

removing the deflated balloon from the blood vessel (the last 5 steps are inherent angioplasty steps).

However, Roger et al remains silent as to the lipophilic bioactive material ("bioactive lipid", page 288 as discussed above) being paclitaxel. Barry et al teaches another drug carrying angioplasty balloon including paclitaxel as the drug for treating restenosis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize paclitaxel as taught by Barry on the angioplasty balloon of Roger et al in order to treat restenosis.

However, Roger et al remains silent as to the balloon having folds, and portions of the dried layer containing paclitaxel are positioned in the folds. Fischell teaches another angioplasty balloon including folds (fig 6) for the purpose of compressing the balloon for delivery. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a folding angioplasty balloon as taught by Fischell on the angioplasty balloon of Roger et al in order to compressing the balloon for delivery. Such a modification inherently meet the portions of the dried layer containing agent are positioned in the folds, since the balloon would be coated prior to folding, so that is could freely unfold when inflated.

With regard to 36, Roger et al as modified inherently inflated the balloon at the treatment site for an inflation time up to about one minute (inherent in that angioplasty is done in 45-60 second inflation times with deflation time in between inflations to allow life giving blood flow). Since, Roger et al remains silent as to the inflation time, if it is not considered inherent it would have been obvious based on the admitted prior practice as outlined above.

With regard to claim 38, wherein the bioactive material further comprises a diagnostic agent (Roger et al -Dye- page 283, col 1, line 28).

With regard to claim 40, angioplasty is on a coronary artery.

With regard to claims 41, 44, 46-48 and 54, However, Roger et al remains silent as to any dosing levels including about 5-500 micrograms. Barry et al teaches another method of delivering a paclitaxel to an interior wall of a blood vessel from an implantable medical device (balloon) in the range of about 5 to about 500 micrograms (200 example 1, 489 table III, 44.8-144.3 table VI, etc…) for the purpose preventing restenosis in a compatible range. The remainder of the range is obvious, since this can be determined by experimentation. It would

have been obvious to one of ordinary skill in the art at the time the invention was made to dose the paclitaxel coating of Roger et al in the range of about 5 to about 500 micrograms in order to compatibly prevent restenosis.

With regard to 43, However, Roger et al as modified remains silent as to the material of the balloon catheter, specifically a polyamide, polypropylene, polyether block amide or polyethylene. It is admitted prior art to use a polyamide, polypropylene, polyether block amide and polyethylene for a balloon membrane in the art of balloon catheters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polyamide, polypropylene, polyether block amide or polyethylene as the balloon catheter member either inherently or as mere substitution of one functionally equivalent balloon material for another within the art of balloon catheters.

With regard to claim 48, Roger et al remains silent as to any dosing levels including a total of about 0.2 to about 20 micrograms of paclitaxel or a paclitaxel derivative per mm2 of the outer surface of the expandable balloon. Barry et al teaches from about 0.2 to about 20 micrograms (.6-4, fig. 1). As before the remained of the range is obvious, since this can be determined by experimentation. As modified above the claim is met.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roger et al (Ceramide-Coated Balloon Catheters Limit Neointimal Hyperplasia After Stretch Injury in Carotid Arteries) in view of Barry et al (6306166) in view of Fischell (6,120,533) as applied to claim 40 above and in further view of Palasis et al (6369039). Roger et al as modified discloses a method as discussed above including a balloon attached to a catheter and inherently includes an inflation lumen for inflating the balloon. However, Roger et al as modified remains silent as to

the catheter includes a guide wire lumen. It is well known in the art of angioplasty balloons to include a guide wire lumen in the balloon catheter for the purpose of guiding a wire to the sight and then passing the catheter over the wire to the sight, as taught in Palasis et al (as previously rejected the guide wire is disclosed in the examples). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a guide wire (at therefore a lumen) as taught by Palasis et al on the balloon catheter of Roger et al in order to guide the device to the sight.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/
Primary Examiner, Art Unit 3774